GUIDANCE ON
SITE SPECIFIC RISK ASSESSMENT
FOR USE AT
CONTAMINATED SITES IN ONTARIO

JULY 1996

Ministry of
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Ontario Ministry of Environment and Energy

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For information pertaining to the Ecological Risk Assessment portion of this document the Phytotoxicology Section, Standards Development Branch should be contacted.

Preface

This document has been prepared for the purpose of giving general guidance on conducting both human health and ecological risk assessments for site clean-ups in Ontario. It is neither a detailed description of the risk assessment process nor a field guide to conducting risk assessments. Information sources that will provide a greater level of detail for those purposes are provided at the end of each part of this document. The reader should refer to the MOEE document "Guideline for the Assessment and Remediation of Contaminated Sites in Ontario", 1996, for details on the selection of the Site Specific Risk Assessment (SSRA) approach as a remedial option.

The document is organized into three parts. Part 1 is a general introduction to the process of risk assessment. It describes the purpose of this document and the role of risk assessment in the site remediation decision making process often followed in Ontario. It also provides guidance for the selection of a qualified individual or group of individuals for the conduct of site specific risk assessment, and formulates MOEE requirements regarding third party review.

Part 2 provides some general guidance for conducting human health risk assessment for the remediation of contaminated sites in Ontario. It is not intended to be an exhaustive guideline or protocol, but a statement of basic principles and general requirements for Human Health Risk Assessment.

Part 3 provides a basic framework for conducting site specific ecological risk assessments for the remediation of contaminated sites in Ontario. As per Part 2, it is not an exhaustive protocol or methodology, but a statement of principles and direction. Reference is made at the end of Part 3 to sources that give more detailed methodologies for the field user.

This document uses concepts and terminology that are consistent with the framework for conducting ecological risk assessments that has been developed by the Canadian Council of Ministers of the Environment (CCME) (CCME, 1996a).

PART 1: INTRODUCTION

Risk assessment is a tool that can be useful for estimating the potential for adverse effects that could arise from the presence of contamination at a site. As such, information derived from risk assessment can be of assistance in determining remediation criteria. The process can also help risk managers evaluate and compare the effectiveness of site specific remedial alternatives and technologies to reduce risk and to design a remediation plan. Risk assessment principles have been utilized extensively in the development of the generic criteria. As the term "generic" implies, these criteria must account for the large majority of situations and, as a result, may not always be appropriate for situations where site specific considerations deviate substantially from the conditions assumed in the generic criteria development process.

It is anticipated that the large majority of site remediations will be based on the use of the generic criteria; however, the guideline allows for the use of risk assessment in the determination of site specific remediation alternatives, irrespective of whether generic criteria exist for the parameters of concern. Proponents choosing to use Site Specific Risk Assessment (SSRA) should be aware that the processes of risk assessment and risk management are necessarily longer than that of utilizing the generic criteria, and that site remediations based on an SSRA approach may result in increased restrictions for future site uses. It should also be noted that the use of SSRA must also fully consider both human and ecological health, with the exception of for sensitive sites where only the sensitive aspect need be addressed, as specified in the guidelines. All relevant pathways and receptors associated with the site must also be considered. Site specific criteria derived from the SSRA process must also fully account for all potential receptors and exposure pathways that were considered in generic criteria development process as detailed in the document "Rationale for the Development and Application of Generic Soil, Groundwater and Sediment Criteria for Use at Contaminated Sites in Ontario" (MOEE, 1996b).

The proponent deciding to utilize SSRA should be aware that, for many parameters, published ecological toxicity data are scarce, and if SSRA is utilized in place of existing criteria, laboratory and field toxicity studies/bioassays may be required. The proponent is required to conduct an ERA and assure that potential ecological receptors, both terrestrial and aquatic, are protected, even if these components have not been covered in the specific generic criterion.

This document is intended to provide guidance on conducting both human health and ecological risk assessments for site remediations in Ontario. It also outlines the general expectations of the Ministry of the Environment and Energy (MOEE) for the planning and conduct of an SSRA. Since each site remediation project is different and decisions may have to be made unique to each circumstance, the provisions are intended to provide general guidance only. Sound scientific judgement must be exercised dutilized throughout the assessment.

This document is not intended to cover the design of community health studies, biological monitoring, nor epidemiological studies.

In conducting an SSRA, the risk assessor should use the principles and approaches contained in the following three documents (or sets of documents):

1. Background Documentation for the Development of the MPC Numerical Standards. Massachusetts Department of Environmental Protection, Bureau of Waste Site Clean-up and Office of Research and Standards. April, 1994.

2) Risk Assessment Guidance for Superfund. Volume 1:Human Health Evaluation Manual (Part A): Interim Final. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Washington, D.C. 1989. EPA/540/1-89/002

3) A Framework for Ecological Risk Assessment: General Guidance. CCME, April, 1996 (c/o Manitoba Statutory Publications, 200 Vaughn St. Winnipeg, Manitoba, R3C-1T5, phone 204-945-4664). A Technical Appendix to this document is to be published soon.

In cases of divergence in guidance provided on specific issues, the requirements outlined in this document should be followed. The risk assessor should clearly highlight and rationalize any departures from these protocols and recognize that this could significantly add to the time required for the review of the SSRA process.

1.1 Use of the SSRA Approach in Site Remediation Activities

When environmental contamination is encountered at a site, a decision is required on what actions must be taken in order to reduce human and ecological health risk. The decision is often based on the evaluation of alternatives (e.g. various remediation levels) in terms of their impact on the health and well being of human and non-human biota, in terms of socio-economic impact, and taking into consideration technical feasibility and legal considerations.

The process leading to a decision on whether to use generic criteria or to select the SSRA approach normally consists of some or all of the following steps:

- assessment of contaminant concentrations relative to generic criteria in the guideline
- identification of any Potentially Sensitive Sites (as defined in the guideline) that could be affected by contaminants on-site
- technical economic feasibility assessment of meeting the appropriate generic criteria

Where the assessment indicates that it is not feasible or economically possible to meet the generic criteria, or on the basis of other considerations, the proponent may decide to proceed

with an SSRA. Where the SSRA approach is selected in lieu of using a generic criterion, it may be used either to modify one or more of the components of the generic criterion, or to develop all components for a site specific criterion.

The administrative requirements for the use of site specific risk assessment are detailed in the main guideline document.

The SSRA approach involves two main components, Risk Assessment and Risk Management. These are briefly described below.

1.2 What is Risk Assessment?

Risk assessment refers to the technical, scientific assessment of the nature and magnitude of risk and uses a factual base to define the health effects of exposure of individuals or populations to hazardous contaminants and situations. It uses tools of science, statistics and modelling to analyze risk-related information. For the purpose of this document, risk is defined as the probability of an adverse event due to disturbances in the environment. One can also describe risk with the following expression.

Risk = Severity of event (Hazard) x Exposure

All ecological and human health endpoints, including both cancer and non-cancer, must be assessed. The quality of the assessment is governed to a large degree by the quality of the supporting toxicological and exposure information and the expertise of the professionals who conduct the assessment. Uncertainty is inherent in the process. Risk assessment is only one of a number of assessment tools that can be applied to a problem. It may be the most appropriate tool in some instances, but may not be the method of choice in others. For some contaminants, it is possible that existing toxicological data do not allow for quantitative risk estimation within a reasonable degree of uncertainty. Under these situations, qualitative assessment would be a minimum requirement but may not necessarily be sufficient for decision making. In these cases, if a generic criterion exists, the proponent may be required to achieve that criterion.

1.3 What is Risk Management?

Risk management refers to the development and implementation of a strategy to control, mitigate or manage the risk. It is the process during which the relative merits of the alternatives are compared to each other and the most appropriate is selected from among them for implementation. Risk management integrates the results from risk assessment, including its uncertainty, with information about technical resources, socio-economic factors, and

control options to reach a decision. This management decision may also include other factors and community input in some cases. The development of alternatives, evaluation of alternatives according to their effects on health and on their impact on socio-economic, technical and legal factors, and comparison of alternatives may form an iterative process. Scientific judgments and policy choices are made based on the best scientific information in the risk assessment process, and are distinct from the broader social and economic policy issues inherent in risk management decisions. It becomes essential to clearly separate the two components of risk assessment and risk management, so that risk managers are provided with risk estimates that are affected as little as possible by non-scientific considerations for making management decisions.

Given the variety of risk management decisions that can be utilized and the impact these decisions can have on the site remediation process as well as on associated administrative requirements, these decisions have been divided into two categories: Level and Level 2 Risk Management.

1.3.1 Level 1 Risk Management

Some risk management decisions are essential to the development of criteria based on the SSRA process. These include such issues as:

- what is an acceptable risk?
- what apportionment of a reference dose to different media should be used in developing the criteria?
- how should normal background concentrations be accounted for?
- how should the SSRA consider analytical capabilities?

The generic criteria in the guidelines were developed based on specified methods of handling the above issues. In using the SSRA approach, the same methods must be adhered to. These are outlined below.

1.3.1.1 Lifetime Cancer Risk

A lifetime additional cancer risk of one-in-a-million (10^{-6}) for carcinogens must be utilized.

1.3.1.2 Apportionment of Reference Dose

In the case of threshold chemicals, any deviation from the 20% apportionment used in the development of the generic criteria must be fully justified via a multimedia exposure assessment.

1.3.1.3 Solubility Ceiling

As was the case for generic criteria, the incorporation of the 50% of solubility limits must be adhered to for parameters in water.

1.3.1.4 Minimum Values for Criteria Developed Based on SSRA

In the development of the generic soil criteria, the numerical values were always limited at the low end by both known background concentrations and analytical capabilities. The same concepts apply to the development of site specific criteria. That is, the values cannot be expected to fall below the background concentrations for uncontaminated parkland sites (as defined within the guideline), nor would they be driven below the method detection limits (MDLs) listed in the document "Guidance on Sampling and Analytical Methods for Use at Contaminated Sites in Ontario" (MOEE, 1996a). Where such numbers are lacking in the guidelines or supporting documentation, they may be developed using methods and principles outlined in the guidelines and in the above document.

1.3.1.5 Maximum Values for Criteria Developed Based on SSRA

In addition to the minimum values described above, the Ministry has developed a set of maximum numeric values for soils and non-potable groundwater which will serve as ceiling or upper concentration limits for site specific criteria developed via SSRA and Level 1 risk management. These values were developed as a precautionary measure to minimize the general degradation of soil and groundwater quality in Ontario, recognizing that once contaminated, it may not be possible or feasible to return these media to pre-contamination levels. It is stressed that these values are absolute maxima that may not be exceeded by criteria derived from an SSRA approach without some form of Level 2 risk management. They are not to be viewed under any circumstances as acceptable or allowable levels, and any numbers used in a remediation that are between these levels and the acceptable generic criteria in the main guidelines must be fully supported. In the case of soils, the Upper Concentration Limit has been set at a level equal to 10 times the highest exposure-related human contact component (S1, S2, S3), with an absolute ceiling of 10,000 ppm (µg/g). For groundwater, the Upper Concentration Limit applies only to the non-potable situation, with the values set at 10 times the highest exposure-related groundwater component (GW-2, GW-3), with an absolute ceiling of 100,000 ppb (µg/L) and adjusted for solubility (50%). Given the direct human health aspect for potable groundwater (based on drinking water objectives), any risk-based Level 1 risk management adjustment of these values would require case specific justification and would not be expected to deviate significantly from the generic criteria.

This process is similar to that used by Massachusetts. Concentrations above these values will not be permitted as site specific criteria resulting from an SSRA without some form of Level 2 risk management. These "Upper Concentration Limits" are presented in Appendix E.

1.3.2 Level 2 Risk Management

Level 2 risk management involves decisions on remediation measures to be used or on minimizing risks that could result from leaving contaminants in place at concentrations higher than either the generic criteria or those determined by the SSRA and Level 1 risk management process. The considerations involved in Level 2 risk management could include:

- the full or partial blocking of exposure pathways,
- limiting site access to certain receptors,
- engineered solutions, and
- socio-economic considerations regarding the level of acceptable risk.

Wherever engineered solutions or blocking of exposure pathways are considered, an additional risk assessment must be conducted to ensure that the residual risk is acceptable. The proponent must also be aware of and abide by the requirements of the main guideline regarding establishing and maintaining appropriate administrative and public consultation requirements.

1.4 Selection of Qualified Consulting Team

Since risk assessment encompasses a broad array of scientific and statistical tools and information, to perform a meaningful risk assessment normally requires a team of professionals with expertise in the various disciplines. The expertise normally includes the following:

- toxicology
- environmental chemistry
- ecology
- hydrogeology
- environmental fate and transport modelling
- epidemiology and community medicine in some cases

The team needs to demonstrate the required expertise and experience, concomitant with the health aspect and environmental data/modelling issues involved.

1.5 Third Party Peer Review

The Ministry requires proponents to have all site SSRAs peer reviewed by a third party prior to proceeding with a remediation plan. The basic requirements are as follows.

- The review must be undertaken by a generally recognized expert or group of experts with demonstrated knowledge of the areas described in Section 1.6. A peer reviewer should restrict her/his comments to specific areas of his/her expertise (e.g. a general expertise in risk assessment does not imply expertise in hydrogeology).

- The third party reviewing the document must be entirely independent of both the consultant conducting the risk assessment and the proponent of the project, with the sole exception of the contract and fees received for conducting the review.

- Documents should be reviewed and documentation revised prior to submission to the Ministry, with a detailed indication of how review comments have been accounted for included in the report.

- The peer review must fully consider the guidance given in this document and point out any discrepancies between the risk assessment and this guidance.

- It is expected that the review will at a minimum encompass the areas outlined in the Checklist for Reviewers (Appendix F), Ministry requirements and any other significant issues impacting on the assessment of health risk. This depth of review should be substantially demonstrated through the provision of a written review report.

PART 2: HUMAN HEALTH RISK ASSESSMENT

2.1 What is Human Health Risk Assessment?

Human health risk assessment is the evaluation of the probability (including likelihood and severity) of adverse health consequences, and the accompanying uncertainties, to humans caused by the presence of a chemical at a given site. The approach takes into consideration that many contaminants may be present simultaneously in several media such as food, air, water, soil or dust and consumer products and that they reach the receptors through multiple exposure pathways.

The first step involves formulating the problem based on the nature and extent of contamination in the media and locations of concern. Routes of contaminant transport due to site specific characteristics must be accounted for. The site is characterized to determine what receptor populations are currently present at or near the site and to identify those that may be present in the proposed land use category. Hazard identification results in a preliminary identification of potential human receptors, potential exposure pathways and potential impact on human health. For certain sites, the list of chemicals that have potential for full assessment may be lengthy. The risk assessor may wish to reduce the number of chemicals to the significant ones to be carried through the remaining three steps of the risk assessment process.

Hazard identification/problem formulation is followed by the determination of the risk associated with the presence of the chemical to the receptors identified at or near the site. This risk is estimated in three major steps; toxicity assessment, exposure assessment and risk characterization.

2.2 When is Human Health Risk Assessment Used?

Within the guidelines for use at contaminated sites in Ontario, Human Health Risk Assessment can be used in the following situations:

- where generic criteria do not exist
- where the use of the generic criteria is not feasible
- at sites where the overburden is less that 2 metres deep. In this case, a Human Health Risk Assessment is required.

Use of Human Health Risk Assessment in the first situation requires an examination of all the components that have been utilized in the development of the generic criteria in the guidelines, whereas, in the latter two situations, it may be possible to examine individual critical components of the generic criteria through the SSRA.

2.3 Principal Elements of Human Health Risk Assessment

There are four major elements that must be considered in human health risk assessment. These elements are listed below.

- Hazard Identification/Problem Formulation

  Determination of whether a particular environmental contaminant is present or is likely to be present and identification of all key adverse effects. Adverse effects include chemical and physical effects (e.g. environmental fate and transport, persistence in the environment, bioaccumulation, etc.), toxicological and other health effects, such as diseases, and aesthetic effects.

- Dose response assessment

  Determination of the quantitative relationship between the magnitude of exposure and the probability of occurrence of a particular adverse effect as well as the uncertainties associated with the determination.

- Exposure assessment

  Determination or estimation of the magnitude, frequency, duration and routes of exposure for the contaminant and assessment of the uncertainties associated with the determination.

- Risk characterization

  Integration of the results of exposure and dose-response assessments to describe the nature and magnitude of the risk from each route of exposure, the population and sub-population at greatest risk and the uncertainties associated with the overall analysis.

2.3.1 Hazard Identification/Problem Formulation

Hazard Identification answers the following questions.

1. Characteristics of the contaminants

   a. What are the potential adverse toxicological and health effects on the receptors associated with chemical exposure?

b. What are the physical effects of the contaminants? (e.g. environmental fate and transport, persistence in the environment, bioaccumulation, etc.)

2. Characteristics of the site

a. What are the general physical characteristics of the site? (e.g. climate, vegetation, soil type, ground water hydrogeology, presence and location of surface water, meteorology, geologic setting, etc.)

b. What is the current land use category? How far away is the closest human population? Is the site publicly accessible? What are the human activities and patterns (e.g. % time the potentially exposed populations spend in the potentially contaminated area; % time the activities occur primarily indoors or outdoors; variation due to seasonal changes; any site-specific population characteristics that might influence exposure, etc.)?

c. What is the future land use category? Would the groundwater be used for drinking in the future (if not used now)?

d. What is the human sub-population of potential concern? Is there any group with increased sensitivity, either due to the behaviour, activity pattern, etc. of the sub-population or to the inherent toxicity of the chemical? How far are they from the site (e.g. schools, day care centres, hospitals, retirement communities, residential areas with children on-site or nearby)?

3. Chemical selection for detailed assessment

a. Which contaminants are required to be subjected to further steps in the risk assessment process; specifically, dose response assessment and exposure assessment? (See Appendix A for Chemical Selection Criteria).

2.3.2 Toxicity Assessment

Toxicity assessment is composed of two components. The first component is addressed under **hazard identification** which is discussed in Section 2.2.1. The second component is **dose response assessment.**

In general, toxicity assessment answers two basic questions:

- What are the potential adverse effects on the receptors associated with chemical exposure? (i.e. **hazard identification**)

- What is the relationship between the magnitude of exposure from different exposure routes and the probability of the occurrence of these adverse effects in the receptors? (i.e. **dose response assessment**)

To answer these questions, the risk assessor examines a wide spectrum of information. This includes human epidemiological studies, animal toxicity studies, and other supportive data, including metabolic and pharmacokinetic studies, cell culture and microorganism studies and structure-activity studies. Usually, all evidence is weighted in deriving an answer to the first question. The dose-response assessment involves many other considerations. These include consideration of the appropriate data set to use, species-to-species extrapolation and high to low dose extrapolation. The dose-response relationship is one of the key pieces of information needed in determining remediation criteria for the chemical(s). The publication by the U.S. National Academy of Science, titled "Risk Assessment in the Federal Government: Managing the Process" contains more detailed questions which should be considered by the risk assessor.

2.3.3 Exposure Assessment

Exposure assessment answers three basic questions:

- What are the pathways by which receptors are potentially exposed?
- What is the frequency and duration of actual and/or potential exposures?
- What is the magnitude of these exposures?

Reasonable maximum as well as average estimates of exposure (or distribution) for relevant populations are developed based on both current and future land use assumptions, and site specific environmental levels. For both current and future land use scenarios, the risk assessor must identify the potential pathways of exposure from all media, estimate the exposure point concentration for specific pathways and quantify the contaminant intake and uptake for specific pathways.

Some of the questions asked and information needed in doing exposure assessment are categorized as follows:

1. Identification of exposure pathways of concern

    a. What are the sources for all potential releases (past, present and future) and what are the potential receiving media (air, surface water, ground water, soil, sediment, biota)?

- This involves evaluation of the physical/chemical, fate and transport properties of the chemical to identify the media that are receiving or may receive the site-related chemical.

b. What are the exposure points? (i.e. where can the potentially exposed population contact the chemical?)

c. What are the exposure routes? (e.g. ingestion of soil, inhalation of vapour, inhalation of soil particles and dust, dermal contact with soil, etc.)

3. Quantification of the exposure to the receptors

This includes the calculation of intake, uptake or delivered target dose rates for each exposure pathway and the total dose rate for each route. It requires the following information:

a. exposure concentration (arithmetic average of and range or distribution of concentration that is contacted over the exposure period) at the exposure points

b. contact rate (amount of contaminated medium contacted per unit time or event) and/or absorption rate

c. total time of exposure (estimated from exposure frequency and duration)

Quantification must also include exposure from other sources/pathways/routes not specifically associated with the contaminated site under assessment, such as food ingestion, water supply and ambient air.

2.3.4 Risk Characterization

In the final step, risk characterization, the information from the exposure assessment and toxicity assessment is integrated. By comparing chemical-specific toxicity information against both measured contaminant exposure levels and levels predicted through fate and transport modelling, a determination is made as to whether current or future levels at or near the site are of potential concern. The population at risk, as well as the magnitude and nature of risk from each major route of exposure are also identified. Risk characterization should include evaluation of the contribution from the different exposure routes and media to the overall risk when appropriate.

It should be noted that there are areas of uncertainty in both toxicity and exposure

assessment. Uncertainty of the overall risk assessment process should be analyzed, quantified (where appropriate) and discussed explicitly. This information, be it overestimation or underestimation, will be factored into the risk management decision in designing a suitable risk reduction strategy. It is in the "Risk Characterization Section" that the risks in terms of magnitudes, types and uncertainties involved are described and their significance interpreted.

2.4 General Requirements of a Human Health Risk Assessment

2.4.1 General features

It is expected that the uncertainty of the assessment be minimized to remain biologically meaningful in order that it can be a useful tool for making meaningful risk management decisions. Efforts should be focused on matters of significance, i.e. matters which could potentially contribute significant uncertainty to the overall assessment.

In general, the site specific risk assessment should:

- Be fully documented.
- Be scientifically defensible. (i.e. a quality equivalent to publication in reputable international journals.)
- Contain the main components of risk assessment, namely; problem formulation/hazard identification, exposure assessment, dose response assessment, risk characterization, and include a discussion of the uncertainty.
- Be conducted in accordance with established acceptable approaches in each scientific and statistical field.
- Provide experimentally measured values to support/verify modelling where available.
- Be based on realistic assumptions substantiated with supporting data. All assumptions should be made explicit. In the absence of sound scientific information to the contrary, the assumptions should err on the side of caution.
- Be carried out by professionals, including scientists qualified in human toxicology.

2.4.2 Hazard Identification & Chemical Selection for Detailed Assessment

This portion of the assessment should address the following requirements:

- Provide basic information on the site, including summary of past and current land use of the site and the surroundings.
- Provide a brief description of the sampling program.
- Before applying any screening method, document a list of contaminants found on site and include a summary of the monitoring data and detection limit for each contaminant. This could include a spacial distribution of contaminants on site when appropriate.
- If screening is involved to reduce the number of chemicals for human health risk assessment, the report must present the chemical selection criteria, the list of chemicals, and how the criteria are applied to the list of chemicals. This is best presented in a tabular form.
- Although the specific criteria for chemical selection are dependent on the site, construction plan and surrounding land use, it is imperative that chemical species present at the site that are relatively toxic, persistent and mobile would not be screened out. (Refer to selection criteria in Appendix A.)
- If human health is the criterion for the selection, then only human-health based soil guidelines should be used for screening. Generic criteria from the guideline which have incorporated other considerations may not be suitable without further examination and additional explanation or adjustment (refer to Appendix A). Instead, exposure limits, such as reference doses (RfDs), allowable intakes or risk specific doses (RsDs), developed by major reputable regulatory agencies with some conservative exposure assumptions would be more suitable. If such values are available, novel interpretation/modification of toxicity parameters will, in general, not be acceptable.
- Provide an analysis and a summary of the potential adverse effects on the human receptors for chemicals selected.

2.4.3 Toxicity Assessment

- The use of probabilistic approaches in dose response assessment is not supported by the MOEE at the present time.

- The RfD, cancer slope or allowable daily intake should be identified for the correct isomer/speciation of the chemical as identified on site, for the routes of exposure of interest. Caution must be exercised in converting the exposure limit for one route of exposure to another, especially when the toxic endpoints are entirely different. Supporting and credible analysis is required.

- In many circumstances, published toxicity assessments by reputable regulatory agencies may be adopted. Such agencies include other Canadian jurisdictions, US Environmental Protection Agency, World Health Organization, California Environmental Protection Agency. In general, the required documentation consists of an evaluation and a description of the toxicity assessment and provision of a rationale for adopting the particular toxicity assessment over the others in terms of choice of database, quality of the assessment, use of up-to-date information and suitability of the assessment in the context of the problem at hand. However, there are currently certain chemicals for which the Ministry has developed health based toxicity values. These MOEE values should be used in lieu of values from other jurisdictions. (refer to Appendix B.)

- Occupational exposure limits (TLVs/OELs) apply strictly to workers under existing labour regulation. The use of TLVs/OELs may not be suitable for environmental risk assessment because occupational exposure limits are generally based on principles and assumptions different from those pertaining to community health based limits. Application of a correction factor to convert an occupational TLV to an environmental limit, where an acceptable environmental limit does not exist, is not generally endorsed unless supported by a complete documented analysis of data.

- Caution must be exercised in the conversion of short term exposure limits to long term exposure limits and vice versa. Note that the toxic endpoints of long and short term exposure can be quite different, and further, may be mediated by different mechanisms. Any conversion factor proposed has to be scientifically supported and fully documented.

- It is inappropriate to convert regulatory guidelines into RfD or RsD or allowable intakes, as other risk management considerations may be incorporated into developing these guidelines. Instead, the background documentation should be consulted to identify the RfD, RsD or allowable intakes developed by the respective regulatory agencies or which form the basis for an existing limit (e.g. drinking water objectives).

- It may not be possible or appropriate to conduct quantitative risk assessment where there are insufficient data or no pre-existing toxicological assessment of the contaminant. In general, when a contaminant has not been assessed and an exposure limit or dose response relationship has not been established by credible agencies, risk

assessment should not be undertaken. *De novo* analysis of toxicity data is highly discouraged and will generally not be accepted.

- Depending on the purpose of the risk assessment, a lack of relevant data should lead to the following conclusions:

  - the present status of scientific knowledge does not allow the evaluation of human health risk

  - no human health based remediation criteria can be established.

  Recommendations can be made that, for the protection of human health and in the absence of adequate knowledge to human health risk, exposure to humans be reduced as much as possible, and remediation criteria be based on other factors (i.e. background). This is within the realm of risk management decisions and is outside the scope of risk assessment.

- An analysis of the major sources of uncertainty on both hazard identification and dose response assessment and of how such uncertainty affects the outcome of the toxicity assessment should be provided.

2.4.4 Exposure Assessment

- Depending on the land use, the construction plan and the surroundings, this section should identify relevant on-site and off-site human receptors that could be affected. This also includes occasional receptors (e.g. visitors, utility workers, etc.) Receptor characteristics, such as age, water and soil intake, should be clearly articulated.

- In the event that the future land use has not been predetermined for a particular site, it should be assumed for the purpose of exposure modelling that the site will be residential in nature. Any departure from this assumption has to be justified.

- For specific contaminants, identify specifically sensitive receptors from toxicity assessments.

- Discuss the environmental fate of the contaminants including possible degradation.

- When sufficient laboratory and field evidence indicates that a chemical could be degraded/biodegraded to a relatively more toxic and persistent intermediate/product, the future concentration of the potential degradation product/intermediate has to be

estimated from the present concentration of its precursors if possible. A good example is the anaerobic biodegradation of chlorinated aliphatics in groundwater.

- Identify direct and indirect pathways of exposure for each receptor.

- Depending on the land use, the construction plan and the fate and transport of the contaminant in the environment, identify and document relevant exposure scenarios, exposure pathways to on-site and off-site human receptors.

- The exclusion of receptors and exposure pathways normally associated with a particular scenario must be fully justified.

- Document the exposure models, model assumptions and characteristics of the receptors, used for evaluation of exposures.

- With regards to the use of computerized exposure models, the MOEE prefers that proponents utilize models available in the public domain. Such models must be accompanied by available technical support documentation of basic principles, user instructions, etc. Use of proprietary models is acceptable only when extensive documentation of the modelling is provided. The documentation should include all mathematical expressions and assumptions used in the model(s). In either case, review of a risk assessment will be facilitated by provision to the reviewer of any computer software being utilized for the exposure calculations. The rationale for the suitability of any chosen model to the problems posed by a site should also be documented.

- Provide general equations and sample calculations for evaluating human exposure for the various pathways.

- Calculate exposures to the different receptors from various pathways identified for different chemicals.

- For many chemicals, especially carcinogens, if experimental animal data are used to establish a dose response relationship for a chronic effect in humans, the chemical is usually administered to the animals starting when they are very young through their normal lifespan. Given the same concentration in a given medium, the dose per body weight for infants, children and adults can vary considerably. Furthermore, the concentration of contaminants can vary during the course of a person's lifetime. To allow for comparison on the same basis, one can calculate the weighted average chronic daily intake (CDI - Appendix C).

- Consideration of background exposures other than exposure to contaminated soil on site should also be discussed with reference to the site specific exposure.

- Probabilistic approach

If probabilistic approach is used, the conduct of the modelling should follow general principles of good practice such as those proposed by Burmaster and Anderson (1994) associated with exposure assessment.

The following lists some additional (not exhaustive) consideration.

Site specific parameters:

- Site specific measured values should be used for deriving statistical distributions for site specific parameters using accepted statistical procedures. Not only should the input distributions be provided but also the raw data on which these distributions are derived need to be provided with the risk assessment. The validity of the assessment depends very much on the validity of these distributions.

- Sensitivity analysis should be provided.

- Insufficient measurement does not allow reliable definition of any parametric distribution. For a parameter that may drive the risk assessment, new field measurements should be undertaken to supply missing information or supplement partial information as much as possible. When additional measurements cannot be conducted, the assessor should choose an alternative approach which would provide a reasonable upper bound estimate to the exposure variable (e.g. use of maximum value, bootstrapping which involves sampling equally all measured values, etc). A discussion of the impact of the uncertainty of the parameter on the overall risk has to be provided.

- When several statistical distributions fit a set of measured values comparably well, modelling can be conducted with all possible distributions in parallel following a sensitivity analysis. A range of the output values can be provided accompanied by a suitable discussion of the uncertainty of the distribution and its effect on the final output. All input distributions used in the modelling have to be reported. Alternatively, the distribution that yields the most conservative output can be used, accompanied with a discussion of the uncertainty of the distribution and its effect on the final output.

Receptor characteristics:

- Statistical distributions published in peer reviewed scientific literature should be consulted when selecting distributions for parameters associated with receptor

characteristics.

- Where different sets of statistical distributions have been published for the same receptor characteristic parameter, one should select the most relevant distribution for the site specific risk assessment.

- Provide an analysis of the major sources of uncertainty and how they affect (quantitatively if possible) the exposure estimates.

2.4.5 Risk Characterization

- Should provide clear, unambiguous statements regarding potential health risks, if any.

- Requires an accurate description and a biologically meaningful interpretation of the risks, not just a numerical listing of the risks.

- Evaluation of the risk estimates should be objective and free of value bias.

- Assessment should attempt to discuss the total risk as well as risk of individual parameters. (e.g. possible effects due to synergism, if applicable.)

- When adequate evidence suggests that some chemicals may act interactively (e.g. synergism, additive) through similar mechanism of action and/or on the same target organs, these chemicals should also be treated as a group where appropriate. Examples are chlorinated dioxins, PCBs, PAHs, some volatile organics. Various jurisdictions have published general guidelines on risk assessment of mixtures, such as Health Canada (1994), US EPA 1986b), CAPCOA (1993). Assessors should use their professional judgment when using these guidelines and in deciding which chemicals should be treated as a group.

- It is not appropriate to add hazard quotients of chemicals for which the exposure limits are based on different adverse effects and mediated by different mechanisms of action.

- When a compound is known to degrade/biodegrade in the environment to relatively more toxic and persistent intermediate/product, any significant health risk due to the biodegradation intermediate/product must be characterized.

- The exposure to the chemical on site should be compared to the exposure limits of the same isomer/speciation of the chemical, corresponding to the same route of exposure.

- Make sure that the human receptor evaluated corresponds to the human population for which the exposure limits are developed. For example, in the case of phenol, an exposure limit has been derived based on developmental effects in the developing fetus when pregnant females are exposed to the chemical. This exposure limit would not be appropriate to characterize risk due to direct exposure to either adult males or children without some discussion or applying a qualifier.

- It is important that intake rates are compared to reference doses that are based on administered doses and uptake rates are compared to reference doses based on uptakes. Adjustment to reference doses for bioavailability should not be made if there are no demonstrable differences in uptake between the media used in the toxicity study and the media for the relevant pathway addressed in the site assessment (Refer to Appendix D).

- For non-threshold effects, such as carcinogenic effects, it is important to present the results in such a way that subsequent Level 1 risk management decisions regarding an acceptable risk level to the public can be made with full knowledge of the impact on the numerical values. For example, soil concentrations corresponding to various risk levels (10^{-4}, 10^{-5}, 10^{-6}, etc.) can be listed.

- If remedial action plans are evaluated for their effectiveness in reducing human health risk, each modification to the exposure scenario and calculations needs to be presented along with the baseline exposure estimates.

- Provide an analysis of the major sources of uncertainty and how they impact (quantitatively if possible) on the overall final risk estimates.

2.5 Comprehensive versus Screening Risk Assessment

What has been described in previous Sections 2.2 and 2.3 are basic elements and requirements for a comprehensive risk assessment which aims at quantifying health risk. The results of this process can be used in conjunction with many other considerations for setting site specific remediation criteria.

Under certain circumstances, before embarking on a comprehensive risk assessment, a risk assessor may wish to conduct a screening risk assessment on the contaminants at the site. A screening risk assessment is a preliminary tool with specific purposes as follows:

- to identify likely absence of potential human health risk

- to determine if a comprehensive risk assessment is needed
- to assist in determining the scope of the comprehensive risk assessment.

For example, a screening risk assessment can be undertaken as part of problem formulation. The results of this process are qualitative only and can be used only in chemical selection, eliminating irrelevant pathways of exposure or irrelevant receptors for further consideration in the comprehensive risk assessment. However, the results have no meaning outside the context of the screening procedure.

Screening risk assessment is similar in principle to comprehensive risk assessment. However, unlike comprehensive risk assessment, it cannot be used for the following purposes:

- to make quantitative estimates of risk to human health
- to develop site specific numerical soil remediation criteria.

2.5.1 Chemical Selection, Exposure Assessment and Toxicity Assessment

Unless specifically stated, a screening risk assessment should have the same general features as a comprehensive risk assessment and guidance for conducting chemical selection, exposure assessment, toxicity assessment should be followed where appropriate. In general, more conservative assumptions regarding exposure and receptor characteristics are made in the conduct of a screening risk assessment. The following lists some of such assumptions and the basic steps that would be undertaken:

- Select the most sensitive receptor appropriate for the chemical.
- Select a simple, plausibly maximum exposure scenario.
- Use the maximum detected concentration of the chemical or total concentration of a related class of chemicals.
- With the above information, calculate plausibly maximal on-site exposure for the chosen receptor for the chosen exposure scenario.
- Compare the maximum exposure to the appropriate exposure limit of the chemical.

2.5.2 Risk Characterization

A screening risk assessment differs from a comprehensive risk assessment in the risk characterization step only in the sense that it cannot provide a quantitative estimate of risk. If the maximum exposure is less than the exposure limit, this suggests that the site probably does not pose a health risk due to the particular chemical and a comprehensive risk assessment is likely not needed. However, if the maximum exposure exceeds the exposure limit, a comprehensive risk assessment is needed to determine if the site poses a health risk using more realistic exposure scenarios and more representative estimates (representing central tendency estimates) in each medium. Otherwise, the risk characterization of a screening risk assessment should have the same general features as in a comprehensive risk assessment.

2.6 Resource Publications on Human Health Risk Assessment

Until such time that the Ministry of Environment and Energy develops comprehensive guidance documents for conducting human health risk assessment, the reader can refer to both the Massachusetts "Background Documentation for the Development of the MCP Numerical Standards", which is contained within the Appendices of the MOEE document "Rationale for the Development and Application of Generic Soil, Groundwater and Sediment Criteria for Use at Contaminated Sites in Ontario" (MOEE, 1996b) and the United States Environmental Protection Agency document titled "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)" (US EPA, 1989b) for more detailed guidance on conducting human health risk assessment. In cases of divergence in guidance provided on specific issues, it is expected that the MOEE guidance will be followed. A list of other useful resource literature on various aspects of human health risk assessment is provided in this section. This is not meant to be exhaustive and does not represent endorsement by MOEE. These documents also contain specific jurisdictional policies and default values which may not be applicable to Ontario. Sound scientific judgement should be exercised in utilizing any of the documents.

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PART 3: ECOLOGICAL RISK ASSESSMENT

3.1 What is Ecological Risk Assessment?

Ecological Risk Assessment (ERA) is a process which attempts to estimate and, where possible, quantify risk posed to the environment and its non-human inhabitants by a given condition. For this guideline, this condition is normally the presence of a chemical at concentrations higher than that of uncontaminated background levels. As in human health risk assessment, ERA is the technical, scientific assessment of the nature and magnitude of the risk attributable to the contaminant and the situation. Risk management is a distinct and separate process by which strategies to control, mitigate or manage the risk are developed and implemented. Risk management integrates the results from risk assessment with information about technical resources, socio-economic and control options in order to reach decisions. It is important that the two processes of ERA and risk management are clearly separated so that risk managers have scientifically based risk estimates upon which to base risk management decisions.

ERAs can be either predictive or retrospective. The former attempts to predict the future effects of a contaminant on an existing environment and is used to determine the potential risk of a chemical prior to its release into the environment. The latter attempts to estimate the effect that a contaminant has already had on the environment, and is used to assist in the determination of remedial procedures. Although ERAs for site remediations are often viewed as primarily retrospective, the predictive component needed to estimate potential effects due to release of chemicals from contaminated areas is crucial for its primary applications in this guideline.

3.2 When is ERA Used?

Within Ontario's revised guideline on contaminated sites, there are two ways by which an ecological risk assessment could be conducted. First, situations may exist where there are environmental considerations outside of those for which the generic criteria were established. These are specified in the guideline document. They are situations where there are specific site conditions not accounted for by the generic criteria or where there is a specific receptor or habitat upon which contaminants on the site could have an effect and which merit special attention not given in the development of the generic criteria. An ERA may (see guideline) be required if the proponent was unable or chose not to remediate to appropriate background (not contaminated) concentrations. The second case occurs when a proponent is bypassing the use of existing generic criteria for any reason outlined in the guideline, or where generic criteria do not exist.

These two situations have differing implications regarding the scope of the ERA that is conducted. For the first situation where there are special receptors, critical habitats, or

special site conditions, the appropriate generic criteria still apply to the site, and the ERA is undertaken solely to ensure that the special receptors will be protected or that the special site conditions are accounted for. The ERA can focus specifically on these receptors and accordingly, has a narrow scope with respect to species and habitats examined. This contrasts with the second situation where existing generic criteria are being bypassed or where criteria do not exist. In this case, the ERA must cover the wide range of species that exist on or near the site, or which, given the specific conditions, should be able to exist on the site.

In most cases, the decision to conduct an ERA will occur after a Phase 2 site assessment has been conducted. Information derived from the Phase 1 and Phase 2 site assessments will provide a basis for planning and conducting the ERA.

3.3 Basic Framework for Conducting ERAs

3.3.1 Levels of Assessment

The MOEE accepts the basic CCME framework for conducting ERAs (CCME, 1996). This framework recognizes that specific conditions at different sites warrant differing levels of effort and complexity in conducting ERAs. Accordingly, it proposes three levels of investigation of potential ecological risk as follows:

1) Screening Level Assessment
2) Preliminary Quantitative Risk Assessment
3) Detailed Quantitative Risk Assessment

1) A Screening Level Assessment (SLA) is a primarily qualitative assessment of the potential environmental risk to specific ecological receptors that have been determined to be of major importance. These are called valued ecosystem components (VECs). An SLA is based primarily on data from literature reviews and from previous or preliminary studies at the site. It should provide sufficient information to determine that remediation is or is not required, or it may provide a basis for determining what level of ERA is required and for focusing more detailed investigations of potential effects.

2) A Preliminary Quantitative Risk Assessment (PQRA) uses a combination of literature information and site specific data collected specifically for ERA purposes to determine preliminary quantitative risk estimates for specified VECs exposed to the substances of concern. It is focused on filling significant data gaps identified at the screening level. Methods used are more complex than for a screening level assessment and are directed at producing quantitative assessments of risk. At this level of assessment, bioassays

can be useful tools for assessing the toxicity of the chemicals present at the site. In the large majority of cases where this level of assessment is used, it should produce sufficient information upon which remediation decisions can be based. In a few cases, data gaps or uncertainty may be of sufficient concern to warrant still more detailed investigations.

3) A Detailed Quantitative Risk Assessment (DQRA) uses more extensive and complicated field assessments and modelling of contaminant movement, exposure pathways, ecosystem characterization and assessment of toxicity to attempt to fill significant data gaps and uncertainties already identified, and to quantitatively assess risk. Bioassays are likely to be important tools in assessing toxicity at this level of assessment.

3.3.2 Necessary Elements of Ecological Risk Assessments

There are four major elements that must be considered within an ERA under this guideline. These elements are listed below along with a brief description of each. They are sometimes viewed as steps, in that ERAs can generally proceed in the sequence as listed; however, there are many feedbacks and overlaps between the different elements.

1) Receptor Characterization.
2) Exposure Assessment
3) Hazard Assessment
4) Risk Characterization

1) Receptor Characterization is the process of identifying the ecological (non-human) receptors of concern (VECs), the effects against which it is desirable to protect the VECs, and the means or pathways specific to each VEC by which it may come into contact with contaminants. The receptor characterization process should answer the following questions:

- What species or habitats (VECs) should the ERA protect?
- What effects should the ERA protect these species against? (referred to as "assessment endpoints")
- What measurements can be used to assess the effect? (referred to as "measurement endpoints")
- What characteristics of the VECs influence their exposure to the potential contaminant?

In ERAs conducted for the purpose of bypassing generic criteria, receptors considered

must include terrestrial plants, terrestrial animals and soil dwelling organisms, aquatic species which could be affected through surface water or ground water discharging to surface water, and avian species that may be affected by contamination at the site.

Receptor characterization has links to both exposure assessment and hazard assessment; therefore, the three steps are not conducted independently of one another.

2) Exposure Assessment is the evaluation of the potential exposure of the VECs to substances determined to be of potential concern. It should answer the following questions:

- What are the chemicals of potential concern to be assessed?
- What are the pathways by which specific VECs are potentially exposed to identified chemicals of potential concern?
- What is the magnitude of the actual or potential exposure?
- What is the frequency of the exposure?
- What is the duration of the exposure?

The principles of exposure assessment for ERA are similar to those that are outlined in Part 1 on exposure assessment for human health risk assessment. Methods used for ERAs (i.e. modelling of contaminant movement) and those used for human health risk assessment should be compatible. If screening of chemicals for full assessment is done, the principles outlined in Appendix A should be followed. The main principle in screening or short-listing chemicals is that all chemicals should be included for full assessment unless there is information that supports exclusion.

3) Hazard Assessment is the process of determining the potential for specified contaminants to cause adverse effects in exposed individuals or populations, and of estimating the relationship between extent of exposure and severity of effects. Hazard assessment answers the following questions:

- What are the potential adverse effects on the VECs associated with exposure to the specific chemicals?
- What are the relationships between the magnitude of exposure from relevant exposure pathways and the probability of occurrence of adverse effects on the receptors?

For the levels of ERA above the screening level assessment, bioassays become important tools for hazard assessment. Where bioassays are conducted, they should be chosen to include species and endpoints that are relevant to the site being assessed and

that are known or thought to be sensitive to the potential contaminants, as well as including generally accepted standardized procedures and species.

4) Risk Characterization is the integration of information derived from receptor characterization, exposure assessment and hazard assessment. It gives an estimate of the degree of risk that is present from specified contaminants to the VECs present, or which will or should be present, at a site. Measured and predicted contaminant concentrations are compared with toxicity information to determine the potential for adverse effects. In determining the magnitude and nature of risk from different sources of exposure, uncertainties are always present. The risk characterization section should also analyze and attempt to quantify the magnitude of uncertainty present in these risk estimates by integrating the uncertainty analyses that should be present in the other sections.

3.4 Concluding Remarks

Part 2 of this document outlines a basic structure for conducting ERAs in Ontario that is founded upon the CCME's ecological risk assessment framework. For detailed descriptions of the steps or components for the different levels of ERA, and for more detailed guidance on conducting ERAs, the reader is referred to the CCME document entitled "A Framework for Ecological Risk Assessment: General Guidance" (CCME, 1996). Additional documents describing the recommended process have been developed by the CCME and should be published later this year (1996). Persons conducting ERAs to meet the Ontario contaminated site guidelines must be familiar with the CCME ERA procedures and documents. These, as well as other documents that may be of assistance in conducting ERAs, are listed in the bibliography following this section.

3.5 Useful References for Conducting ERAs

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APPENDIX A

Chemical Selection Criteria

Chemical Selection Criteria

A. Selection criteria for short listing of chemicals

1. Chemicals for which monitoring data indicate "< detection limit", as long as detection limits are acceptable to MOEE, are considered not present on site and are not subject to further investigation. The Ministry has defined its position on Method Detection Limits (MDLs) in the document "Guidance on Sampling and Analytical Methods for use at Contaminated Sites in Ontario" (MOEE, 1996a). This document is a companion document to the revised (1996) contaminated sites guideline.

2. All compounds present at concentrations which exceed effects-based generic criteria must be considered for full risk assessment; however, the criteria in the document "Rationale for the Development and Application of Generic Soil, Groundwater, and Sediment Criteria for Use at Contaminated Sites in Ontario" (MOEE, 1996b) that accompanies the guideline can be used to reduce the number of chemicals for full assessment. For example, a full human health risk assessment may not be necessary for a compound for which the generic criterion was based on ecological effects if concentrations on-site do not exceed the appropriate human health component value. However, it must be noted that, if an exposure pathway important in the site specific case has not been considered in the derivation of the generic soil criterion, an additional component corresponding to that particular pathway should be included (i.e. volatility of the chemical needs to be considered if a major pathway is inhalation).

   For sites identified as potentially sensitive according to the definitions in the guideline, all chemicals present at above background concentrations (Table F in the guideline) must be considered for the appropriate form of risk assessment.

3. All known or probable human carcinogens and chemicals for which no human health threshold has been established for their adverse effect must be evaluated.

4. Compounds which have the potential to bioaccumulate and are also persistent and toxic must be evaluated.

5. For compounds that have the potential to be degraded to other toxic chemicals, the breakdown products must be assessed.

6. The presence of contamination in the ground water but not in soil samples does not preclude the contaminant from assessment, irrespective of the origin of contamination.

7. Where two or more compounds that are similar in physical, chemical, and biological properties and that have the same toxic end points are present in the short list, it is acceptable to evaluate one representative compound to reduce the scope of the exercise. However, if this route is taken, modelling has to be conducted with the most toxic compound, using the highest concentration among the chemicals and the physical chemical properties of the most mobile chemical in the group. If the outcome suggests a health or ecological risk , it would be necessary to re-model the individual chemicals in the group with their corresponding concentrations and the whole group where appropriate.

These are general screening criteria although the specific criteria for screening are dependent on the particular case, the site and the plan for construction, redevelopment, remediation and reuse.

B. Application of criteria

No particular selection criterion has been given greater weight than any other. All must be applied to a given contaminant.

APPENDIX B

MOEE Human Health Based Toxicity Values

MOEE Human Health Based Toxicity Values

Currently, there are certain chemicals for which the Ministry has developed health based toxicity values. These values should be used in preference to values from any other jurisdictions.

Dioxins and Furans

Tolerable Daily Intake (TDI) for 2,3,7,8-TCDD or its toxicity equivalent (TEQ)
= 10 picogram TEQ per kg body weight per day

Although the recommended TDI is developed based on the effects of 2,3,7,8-TCDD, it is possible to calculate tolerable levels of exposure for all dioxins and furans. This is done by taking the concentrations of the 17 most toxic dioxins and furans, multiplying each one by a toxic equivalency factor (TEF) - its toxicity relative to 2,3,7,8-TCDD - and adding up all the corrected concentrations expressed as 2,3,7,8-TCDD toxic equivalents. The international Toxicity Equivalency Factors (I-TEF) of these 17 most toxic dioxins and furans are provided in Table B-1 and are based on the proposal by NATO-CCMS (1988). These values were developed by scientific experts in several countries and were adopted by Canada in 1990.

Lead

Total intake of concern (IOC) = 1.85 µg per kg body weight per day
for sensitive populations within the community

N-Nitrosodimethylamine (NDMA)

Cancer slope factor = 51 per mg/kg/day
for a lifetime exposure

Table B-1 International Toxicity Equivalency Factors for the 17 dioxin and furan isomers of concern (NATO-CCMS, 1989).

Isomer of Concern	I-TEF
2,3,7,8-Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD)	1.0
1,2,3,7,8-Pentachlorodibenzo-p-dioxin (1,2,3,7,8-P5CDD)	0.5
1,2,3,4,7,8-Hexachlorodibenzo-p-dioxin (1,2,3,4,7,8-H6CDD)	0.1
1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin (1,2,3,7,8,9-H6CDD)	0.1
1,2,3,6,7,8-Hexachlorodibenzo-p-dioxin (1,2,3,6,7,8-H6CDD)	0.1
1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin (1,2,3,4,6,7,8-H7CDD)	0.01
1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin (1,2,3,4,6,7,8-OCDD)	0.001
2,3,7,8-Tetrachlorodibenzofuran (2,3,7,8-TCDF)	0.1
2,3,4,7,8-Pentachlorodibenzofuran (2,3,4,7,8-P5CDF)	0.5
1,2,3,7,8-Pentachlorodibenzofuran (1,2,3,7,8-P5CDF)	0.05
1,2,3,4,7,8-Hexachlorodibenzofuran (1,2,3,4,7,8-H6CDF)	0.1
1,2,3,7,8,9-Hexachlorodibenzofuran (1,2,3,7,8,9-H6CDF)	0.1
1,2,3,6,7,8-Hexachlorodibenzofuran (1,2,3,6,7,8-H6CDF)	0.1
2,3,4,6,7,8-Hexachlorodibenzofuran (2,3,4,6,7,8-H6CDF)	0.1
1,2,3,4,6,7,8-Heptachlorodibenzofuran (1,2,3,4,6,7,8-H7CDF)	0.01
1,2,3,4,7,8,9-Heptachlorodibenzofuran (1,2,3,4,7,8,9-H7CDF)	0.01
1,2,3,4,6,7,8,9-Octachlorodibenzofuran (1,2,3,4,6,7,8,9-OCDF)	0.001

APPENDIX C

Calculation of Weighted Average Chronic Daily Intake (CDI)

Calculation of Weighted Average Chronic Daily Intake (CDI)

The weighted chronic daily intake (CDI) is the estimated daily intake averaged over a lifetime and adjusted for body weight. This is useful, especially in the case of carcinogens, for which the dose response relationship is usually developed based on chronic exposure throughout a receptor's lifetime. In situations where the level of exposure of an individual to a given contaminant differs vastly during the course of his/her lifetime, either due to differing environmental levels or body weight or behaviour, calculating the weighted chronic daily intake of the individual allows comparison of the individual's exposure against the health based toxicity values on a common basis.

In general, the equation for calculating the weighted average chronic daily intake (CDI) is expressed as follows:

$$\text{chronic daily intake} = \sum_{i=1}^{n} (\text{Daily intake}_i \times \text{years}_i)/(\text{body weight}_i \times \text{normal life span}).$$

where i = stage of an individual's life
Σ year$_i$ = normal lifespan

Example

Individuals experience a higher level of exposure during the first 7 years of his/her life per unit body weight.

The daily intake of the contaminant for children (1-7 years old) is 1.6 µg/day.

The daily intake of the contaminant for older children and adults (> 7 years old) is 0.4 µg/day.

Assuming the normal lifespan to be 70 years, the average body weight of the child (1-7 years) to be 15 kg and the average body weight of older children and adults to be 70 kg, the weighted average chronic daily intake (CDI) can be calculated as follows.

$$\text{CDI} = \frac{\text{intake(child)} \times 7\ \text{yr}}{15\ \text{kg} \times 70\ \text{yr}} + \frac{\text{intake(adult)} \times 63\ \text{yr}}{70\ \text{kg} \times 70\ \text{yr}}$$

$$= \frac{1.6\ \mu\text{g/day} \times 7\ \text{yr}}{15\ \text{kg} \times 70\ \text{yr}} + \frac{0.4\ \mu\text{g/day} \times 63\ \text{yr}}{70\ \text{kg} \times 70\ \text{yr}}$$

$$= 0.016\ \mu\text{g/ kg/day}.$$

APPENDIX D

Numerical Adjustments for Absorption and Bioavailability

Numerical Adjustments for Absorption and Bioavailability

It is now a common practice for adjustments to be made in exposure assessments to calculated intakes to account for differential absorption efficiency under differing conditions or for differences in the fraction of contaminant which is bioavailable in the matrix of exposure. Such numerical modifications may be necessary in characterizing risk associated with a given site to ensure that intakes or doses are described in the same units as the toxicity values (e.g. RfDs, RsDs) against which the calculated intakes are confronted. Numerical modifications may also be necessary to account for different media of exposure (e.g food, water, soil). This appendix provides some simple rules and examples of how such numerical adjustment should normally be made.

Basic Principles

- for risk characterization purposes, exposure and toxicity values should **both** be expressed either as absorbed doses (uptakes) or as administered doses (intakes)

- adjustments for bioavailability in various media should only be made where differences due to variation in media matrices are meaningfully greater than other receptor influences on the uptake (e.g individual variation in nutritional status).

- do not convert exposure estimates to absorbed dose if toxicity values are based on administered dose.

- conversions for bioavailability should only be undertaken on the basis of strong observational data from human and/or animal studies, and not on model prediction or assumption.

Example 1 Conversion of an estimated intake to an absorbed dose

According to the exposure assessment, the calculated intake of chemical from direct soil ingestion by an individual is 60 µg/kg/day.

The oral RfD or RsD is based on an **absorbed** dose or uptake, not administered dose or intake.

The human absorption factor from soil is known to be 15%.

The converted exposure, expressed as an absorbed dose (uptake) is:

60 µg/kg/day x 0.15 = 9 µg/kg/day

This can be compared directly with the RfD (based on absorbed dose) for this chemical.

Example 2 Conversion of an administered dose RfD to an absorbed dose RfD

An absorbed dose (uptake) has been calculated from the exposure assessment.

The oral RfD of this particular chemical is 5.0 mg/kg/day. This value is **unadjusted** for absorption.

Other data indicate or suggest a 15 % absorption efficiency from the GI tract in the species upon which the RfD is originally derived.

The adjusted RfD, which would be compared to the estimated absorbed dose or uptake, would be:

5.0 mg/kg/day x 0.15 = 0.75 mg/kg/day.

Example 3 Conversion of Slope Factors

Similarly, slope factors for carcinogens must be corrected where exposure estimates have been adjusted for absorption.

For example, an inhalation slope factor, unadjusted for absorption is 5.8 $(\mu g/kg/day)^{-1}$.

Experimental data or assumptions indicate a 50 % absorption efficiency from the lung in the species from which the slope factor is derived.

The adjusted slope factor which would correspond to the estimated absorbed dose is:

$5.8\ (\mu g/kg/day)^{-1}/0.50 = 11.6\ (\mu g/kg/day)^{-1}$

This adjusted slope factor would be used to estimate the cancer risk associated with the absorbed dose estimated in the exposure calculations.

Example 4 Conversions Based on Different Media of Exposure

Often the medium of exposure in the site assessment differs from the media of exposure utilized in the experiments upon which the toxicity value is based. For example, a RfD or other toxicity value may be based on or adjusted for exposure via drinking water, while it is soil ingestion which is being assessed. An adjustment would have to be made to the RfD for a chemical whose absorption may be greatly reduced if present in soil as compared to being present in drinking water because the chemical does not readily desorb from soil in the GI tract. In the absence of reliable scientific information for making these adjustments based on relative absorption efficiencies, it should be assumed that the relative absorption efficiency between food or soil and drinking water is 1.0.

An example of this type of adjustment is as follows.

The estimated daily exposure to a contaminant in soil is 2 mg/kg/day

The oral RfD for this substance is based on drinking water.

The absorption of this chemical from drinking water is known to be 80% and the absorption of the substance from soil is demonstrated to be roughly 40%. The relative absorption in soil/drinking water is therefore 40/80 or 0.5.

The adjusted soil exposure estimate comparable to the RfD based on drinking water is:

2 mg/kg/day x 0.5 = 1 mg/kg/day.

APPENDIX E

Upper Concentration Limits

The Ministry has developed a set of maximum numeric values for soils and groundwater which will serve as ceiling or upper concentration limits for site specific criteria. These values were developed as a precautionary measure to minimize the general degradation of soil and non-potable groundwater quality in Ontario, recognizing that once contaminated, it may not be possible or feasible to return these media to pre-contamination levels. It is stressed that these values are absolute maxima which may not be exceeded by criteria developed through an SSRA process without some form of level 2 risk management. They are not to be viewed under any circumstances as acceptable or allowable levels, and any numbers used in a remediation that are between these levels and the acceptable criteria in the main guidelines must be fully supported.

Appendix E: Upper Concentrations Limits for Soil and Groundwater

Chemical Compound	Upper Concentration Limit for Soil (ug/g)	Upper Concentration Limit for Non-Potable Groundwater (ug/L)
ACENAPHTHENE	10,000	1700
ACENAPHTHYLENE	10,000	2000
ACETONE	10,000	100,000
ALDRIN	1.5	8.5
ANTHRACENE	10,000	120
ANTIMONY	440	100,000
ARSENIC	10,000*	4,800
BARIUM	10,000*	100,000
BENZENE	2,300	100,000
BENZO(a)ANTHRACENE	7,200	5
BENZO(a)PYRENE	72	1.9
BENZO(b)FLUORANTHENE	720	7
BENZO(g,h,i)PERYLENE	7,200	0.13
BENZO(k)FLUORANTHENE	720	0.4
BERYLLIUM	31	530
BIPHENYL, 1,1-	10,000	17,000
BIS(2-CHLOROETHYL)ETHER	6.6	100,000
BIS(2-CHLOROISOPROPYL)ETHER	93	100,000
BIS(2-ETHYLHEXYL)PHTHALATE	10,000	650
BORON	N/V	100,000
BROMODICHLOROMETHANE	900	100,000
BROMOFORM	7,100	100,000
BROMOMETHANE	7,200	32,000
CADMIUM	830	110
CARBON TETRACHLORIDE	430	100,000
CHLORDANE	53	280
CHLOROANILINE, p-	4,400	1,000
CHLOROBENZENE	10,000	12,000

These values are absolute maxima which may not be exceeded without some form of level 2 risk management. Under no circumstances are they to be considered as acceptable or allowable levels. The use of site-specific numeric criteria above the appropriate generic numbers in the main guideline Tables A - D must be fully supported by a complete site-specific risk assessment.

Chemical Compound	Upper Concentration Limit for Soil (ug/g)	Upper Concentration Limit for Non-Potable Groundwater (ug/L)
CHLOROFORM	5,200	100,000
CHLOROPHENOL, 2-	10,000	100,000
CHROMIUM (TOTAL)	10,000*	20,000
CHROMIUM (VI)	10,000*	1,100
CHRYSENE	720	3
COBALT	10,000*	1000
COPPER	10,000*	230
CYANIDE	3,900	520
DIBENZO(a,h)ANTHRACENE	720	0.25
DIBROMOCHLOROMETHANE	670	100,000
DICHLOROBENZENE, 1,2- (o-DCB)	5,000	100,000
DICHLOROBENZENE, 1,3- (m-DCB)	5,000	100,000
DICHLOROBENZENE, 1,4- (p-DCB)	2,300	100,000
DICHLOROBENZIDINE, 3,3-	27	1,600
DDD	130	300
DDE	89	20
DDT	89	1.6
DICHLOROETHANE, 1,1-	5,000	100,000
DICHLOROETHANE, 1,2-	610	100,000
DICHLOROETHYLENE, 1,1-	91	100,000
DICHLOROETHYLENE, CIS-1,2-	5,000	100,000
DICHLOROETHYLENE, TRANS-1,2-	10,000	100,000
'DICHLOROPHENOL, 2,4-	940	37,000
DICHLOROPROPANE, 1,2-	450	100,000
DICHLOROPROPENE, 1,3-	170	24,000
DIELDRIN	1.5	18
DIETHYL PHTHALATE	10,000	300
DIMETHYL PHTHALATE	10,000	300
DIMETHYLPHENOL, 2,4-	10,000	100,000
DINITROPHENOL, 2,4-	940	15,000

These values are absolute maxima which may not be exceeded without some form of level 2 risk management. Under no circumstances are they to be considered as acceptable or allowable levels. The use of site-specific numeric criteria above the appropriate generic numbers in the main guideline Tables A - D must be fully supported by a complete site-specific risk assessment.

Chemical Compound	Upper Concentration Limit for Soil (ug/g)	Upper Concentration Limit for Non-Potable Groundwater (ug/L)
DINITROTOLUENE, 2,4-	66	23,000
DIOXIN/FURAN (ng TEQ/g soil)	10	0.00015
ENDOSULFAN	56	5.6
ENDRIN	150	0.2
ETHYLBENZENE	10,000	100,000
ETHYLENE DIBROMIDE	0.2	100,000
FLUORANTHENE	10,000	130
FLUORENE	10,000	2,900
HEPTACHLOR	6.8	0.4
HEPTACHLOR EPOXIDE	3.3	180
HEXACHLOROBENZENE	28	370
HEXACHLOROBUTADIENE	390	930
HEXACHLOROCYCLOHEXANE, GAMMA	23	8
HEXACHLOROETHANE	470	54,000
INDENO(1,2,3-cd)PYRENE	720	0.27
LEAD	10,000	320
MERCURY	570	1.2
METHOXYCHLOR	3,000	3
METHYL ETHYL KETONE	10,000	100,000
METHYL ISOBUTYL KETONE	10,000	100,000
METHYL MERCURY	180	1.2
METHYL TERT BUTYL ETHER	5,000	100,000
METHYLENE CHLORIDE	7,400	100,000
METHYLNAPHTHALENE, 2-	10,000	13,000
MOLYBDENUM	10,000*	73,000
NAPHTHALENE	10,000	62,000
NICKEL	7,100	16,000
PENTACHLOROPHENOL	430	24,000
PETROLEUM HYDROCARBONS (gas/diesel)	10,000	100,000
PETROLEUM HYDROCARBONS (heavy oils)	10,000	100,000

These values are absolute maxima which may not be exceeded without some form of level 2 risk management. Under no circumstances are they to be considered as acceptable or allowable levels. The use of site-specific numeric criteria above the appropriate generic numbers in the main guideline Tables A - D must be fully supported by a complete site-specific risk assessment.

Chemical Compound	Upper Concentration Limit for Soil (ug/g)	Upper Concentration Limit for Non-Potable Groundwater (ug/L)
PHENANTHRENE	7,200	630
PHENOL	10,000	100,000
POLYCHLORINATED BIPHENYLS	250	1.5
PYRENE	10,000	0.4
SELENIUM	10,000	500
SILVER	2,400	12
STYRENE	1,000	100,000
TETRACHLOROETHANE, 1,1,1,2-	180	100,000
TETRACHLOROETHANE, 1,1,2,2-	24	100,000
TETRACHLOROETHYLENE	10,000	84,000
THALLIUM	1,500	4,000
TOLUENE	10,000	100,000
TRICHLOROBENZENE, 1,2,4-	6200	6,200
TRICHLOROETHANE, 1,1,1-	5,000	100,000
TRICHLOROETHANE, 1,1,2-	120	100,000
TRICHLOROETHYLENE	1,400	100,000
TRICHLOROPHENOL, 2,4,5-	10,000	6,300
TRICHLOROPHENOL 2,4,6-	2,200	100,000
VANADIUM	10,000*	2,000
VINYL CHLORIDE	19	550
XYLENES	10,000	100,000
ZINC	10,000	11,000
ELECTRICAL CONDUCTIVITY (mS/cm)	N/V	N/V
NITRATE	N/V	N/V
NITRITE	N/V	N/V
SODIUM ADSORPTION RATIO (SAR)	N/V	N/V

N/V = No Value.
* = there is no human health based soil contact number: therefore, number defaults to ceiling value.

These values are absolute maxima which may not be exceeded without some form of level 2 risk management. Under no circumstances are they to be considered as acceptable or allowable levels. The use of site-specific numeric criteria above the appropriate generic numbers in the main guideline Tables A - D must be fully supported by a complete site-specific risk assessment.

APPENDIX F

Checklist for Reviewers

These values are absolute maxima which may not be exceeded without some form of level 2 risk management. Under no circumstances are they to be considered as acceptable or allowable levels. The use of site-specific numeric criteria above the appropriate generic numbers in the main guideline Tables A - D must be fully supported by a complete site-specific risk assessment.

Checklist for Reviewers

This appendix provides guidance for reviewing a site-specific risk assessment report. The following is a checklist of many essential features that should be adequately addressed in any good risk assessment. The checklist touches on issues that are often problematic. However, this is not a complete listing of all potential concerns and some of the criteria may not be necessary for all site-specific risk assessment reports. This checklist is intended only as a tool to assist in the general review process and is **not** a replacement for sound judgment on the part of the reviewer.

A. Human Health Risk Assessment

This checklist is a modification of the US EPA's reviewer checklist as described in the document "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)" (US EPA, 1989).

1.0 General

- Were the site-specific objective(s) of the risk assessment stated?
- Was the scope of the assessment described (e.g. in terms of the complexity of the assessment and rationale, data needs, and overview of the study design)?

2.0 Hazard Identification/Problem Formulation

2.1 Site Characteristics

- Was an adequate history of site activities provided, including a chronology of land use (e.g. specifying agriculture, industry, recreation, waste deposition, and residential development at the site)?
- Was a general map of the site depicting boundaries and surface topography included, which illustrates site features, such as fences, ponds, structures, as well as geographical relationships between specific potential receptors and the site?
- Were the current and future land use identified and adequately described?
- Was a qualitative overview of the nature of contamination included (e.g. specifying in a general manner the potential or suspected sources of contaminants, types and

concentration of contaminants detected at the site, media potentially contaminated as well as potential exposure pathways and receptors)?

- Were key site characteristics documented?

  - soil/sediment parameters (e.g. particle size, pH, redox potential, soil type, organic carbon and clay content, bulk density, porosity)

  - hydrogeological parameters (e.g. hydraulic gradient, pH/Eh, hydraulic conductivity, location, saturated thickness, direction, and rate of flow of aquifers, relative location of bedrock layer)

  - hydrological parameters (e.g. hardness, pH, dissolved oxygen, temperature, total suspended solids, flow rates, and depths of rivers or streams; estuary as well as lake parameters such as area, volume, depth)

  - meteorological parameters (e.g. direction of prevailing wind, average wind speed, temperature, humidity, annual average and 24 hour maximum rainfall)

2.2 Data Collection

- Was there a statement specifying both the qualitative and quantitative nature of the sampling data, in terms of relative quality and adequacy for use for the intended objectives of the study?

- Were all appropriate media sampled?

  - was there adequate justification for any omissions?

- Were all key areas sampled, based on all available information?

- Did sampling include media along potential routes of migration (e.g. between the contaminant source and potential future exposure points)?

- Were sampling locations consistent with nature of contamination (e.g. at the appropriate depth)?

- Were sampling maps provided, indicating the location, type, and numerical code of each sample?

- Were sampling efforts consistent with field screening and visual observations in locating "hot spots"?

- Did sampling include appropriate QA/QC measures (e.g. replicates, travelling blanks, travelling spiked blanks)?

- If background samples were collected, were they collected from appropriate areas (e.g. areas proximate to the site, free of potential contamination by site chemicals or anthropogenic sources, and similar to the site in topography, geology, meteorology, and other physical characteristics) using methodologies consistent with the development of Ontario OTRs?

2.3 Data Evaluation

- Were appropriate analytical methods, i.e. in accordance with the MOEE document "Guidance on Sampling and Analytical Methods for Use at Contaminated Sites in Ontario" (MOEE, 1996a), employed for collection of data upon which risk estimates are based?

- Where monitoring data for specific chemicals indicated "< detection limit", were the method detection limits for these chemicals acceptable to the Ministry as defined in the document "Guidance on Sampling and Analytical Methods for Use at Contaminated Sites in Ontario" (MOEE, 1996a)?

- Were any site-related chemicals eliminated without appropriate justification?

  - as infrequently detected chemicals

  - as common laboratory contaminants even though sample concentrations were significantly higher than that found in blanks?

  - as present at a "ubiquitous level"?

- Were inappropriate "proxy concentrations" assigned to site-related chemicals?

  - was a value of zero or half the method detection limit (MDL) assigned?

  - was an erroneous sample-specific quantitation employed?

- Were uncertainties, limitations and gaps in the quality of collection or analysis adequately addressed?

2.4 Contaminants Selected for detailed analysis

- If screening is involved to reduce the number of chemicals for detailed risk assessment,

were criteria for chemical selection provided? Were the criteria consistent with the general guidance provided in Appendix A, appropriate for the site and for the specific problem at hand?

- Were the chemical selection criteria appropriately applied to the list of contaminants found on site and was the application well documented?

- Was the exclusion of any chemical from detailed analysis unjustified? Should any contaminants excluded as a result of the chemical selection process be considered for evaluation?

- Was an analysis of the potential adverse effects on the human receptors for chemicals provided? Was the analysis appropriate?

3.0 Toxicity Assessment

- Were appropriate toxicity values employed based on the nature of exposure?

  - were subchronic vs. chronic RfDs applied correctly based on the duration of exposure?

  - did the toxicity values utilized correspond with the correct isomer/speciation of the chemical identified on site?

  - did the toxicity values utilized correspond with the route of exposure of interest? Were appropriate "route-to-route" extrapolations performed in cases where a toxicity value was applied across differing routes of exposure?

  - were the toxicity values used appropriate for the receptor of interest?

  - were all sensitive subpopulations, such as pregnant or nursing women potentially requiring developmental RfDs, considered in the selection of the toxicity values used?

- If a toxicity value has been adopted from other reputable regulatory agencies, was the basis for the toxicity value provided? Was an explanation provided for the selection of the chosen toxicty value as compared to other existing values, in terms of the quality of the toxicity assessment from which these values were derived, data selection, methodologies, assumptions and how current the assessment was? Was the choice appropriate? Were the values used coonsistent with the values contained within the documentation of the agency from which the toxicity value was adopted?

- In the case of insufficient toxicity assessment, was the conclusion appropriately based on appropriate guidance?

- Were the sources and the impact of uncertainty adequately characterized?

4.0 Exposure Assessment

- If deterministic approach is used in the conduct of the exposure assessment, were average as well as "reasonable maximum exposures" (i.e. the highest exposures that are reasonably expected to occur) considered? Were the point estimates of contaminant concentration supported by the monitoring data?

- If a probabilistic approach is used in the conduct of the exposure assessment, were any significant distributions supported by appropriate monitoring/survey data? Were the data qualitatively and quantitatively adequate for describing a distribution?

- Were current and future land uses considered?

- Was residential land use considered as potential future land use when no decision has been made regarding the use of the site ? if not, was a valid rationale provided?

- Were both on-site and off-site receptors (i.e. including occasional receptors) considered?

- Were all potential sensitive subpopulations considered (e.g. elderly people, pregnant or nursing women, infants and children, and people with chronic illnesses)?

- Were all significant contaminant sources considered?

- Were all potential contaminant release mechanisms considered, such as volatilization, fugitive dust emission, surface runoff, leaching to ground water, tracking by humans/animals, and soil gas generation?

- Were all potential contaminant transport pathways considered, such as direct air transport downwind, diffusion in surface water, surface water flow, ground-water flow, and soil gas migration?

- Were all relevant cross-media transfer effects considered, such as volatilization to air, wet deposition, dry deposition, ground-water discharge to surface?

- Were all media potentially associated with exposure considered?

- Were all relevant site-specific characteristics considered, including topographical, hydrogeological, hydrological, and meteorological parameters?

- Were all possible exposure pathways, direct and indirect, considered?
  - was a valid rationale offered for exclusion of any potential pathways from quantitative evaluation?
- Were all "spatial relationships" adequately considered as factors that could affect the level of exposure (e.g. hot spots in an area that is frequented by children, exposure to ground water from two aquifers that are not hydraulically connected and that differ in the type and extent of contamination)?
- Were appropriate values used in exposure calculations (e.g. age-specific body weights, appropriate exposure frequency and duration values)?
- If exposure models are used in exposure calculation, were all major model characteristics and assumptions provided? Were they appropriate? Was the model appropriate for use?
- Were general equations and sample calculations provided? Were the calculations conducted without error?
- Has background exposure (i.e. other than that originating from the contaminated site) been incorporated in the total exposure or put in context with site specific exposure?
- In the conduct of a screening risk assesment, was the plausible maximal on-site exposure calculated for the most sensitive receptor using a simple maximal exposure scenario? Was the maximum detected concentration of a contaminant or sum of maximum concentration of a related class of chemicals used in the calculation?
- Was uncertainty adequated addressed?

5.0 Risk Characterization

- Were exposure estimates and toxicity values consistently expressed as either intakes or uptakes for each chemical carried through risk characterization?
- Were all site-related chemicals that were analyzed in the exposure assessment considered in characterization?
  - were inconsistencies explained?
- Were risks appropriately summed only across exposure pathways that affect the same individual or population subgroup, and that result in the same adverse effects and mediated by the same mechanism of action?

- When remediation action plans were evaluated for their effectiveness in reducing human health risk, were risk calculations presented for each modification to the exposure scenario?

- Was the description and interpretation of the risk, unambiguous, appropriate, objective and well supported?

- Were sources of uncertainty adequately characterized?

6.0 Overall Document

- Was the documentation of the risk assessment report adequate in addressing the human health risk arising from the contaminated site?

- Were all assumptions made explicit? Were the assumptions appropriate and supported with suitable data?

- Did the conduct of the risk assessment follow sound scientific principles?

- Was the assessment scientifically defensible and of sufficient quality?

- If the maximum exposure exceeded the exposure limit in a screening risk assessment, was it followed up with a comprehensive risk assessment?

B. Ecological Risk Assessment

Since the basic principles of ERA are similar to those of Human Health Risk Assessment (HHRA), and since the quality of both are dependent upon the quality of information provided in the site assessments, most of the checklist for HHRA provided in the previous section of this Appendix is applicable to ERA. Specifically, all of the items listed in Sections 1, 2, 4, 5, and 6 can be applied to reviews of ERAs. In ERA, the CCME protocols that are used in this document refer to Hazard Assessment rather than Toxicity Assessment, as in HHRAs, but the main principles behind the items listed in Section 3 of the HHRA checklist are applicable to the reviews of ERAs, where the species of concern are non-human.

The reviewer of an ERA has a number of items that are additional to the above listings to consider. The main points are listed as follows:

1.0 Receptor Characterization

- Is the level of organization (individual, population, community, ecosystem) of importance

properly identified?

- Are the valued ecosystem components (VECs) chosen as the focus for the ERA appropriate, and have VECs from all relevant groups (i.e. terrestrial mammals, plants, aquatic species, birds, etc) been considered?

- Have receptors that may not be present, but should be present (i.e. they may have been eliminated by the contaminants of concern) been considered?

- Have the structural attributes of the VECs (population, density, age, status (i.e. rare) been properly characterized?

- Have the functional attributes of the VECs (food type, ingestion rates, activity, bioaccumulation) been properly characterized?

2.0 Hazard Assessment

- Is the list of target chemicals appropriate and well founded, considering the attributes of the VECs?

- Are toxicity values derived or chosen from the literature appropriate and relevant to the VECs?

- Are the assessment endpoints chosen appropriate?

- Are the measurement endpoints chosen appropriate and do they adequately reflect the assessment endpoints?

- Has the potential for synergistic effects of mixtures of chemicals been appropriately considered?

- Where bioassays have been used, are the species chosen sufficiently sensitive, do they appropriately reflect the sensitive species that may occur on the site, and is the battery of tests sufficiently broad?

- Are the methods used for bioassays appropriate and defensible?

3.0 Exposure Assessment

The items listed in Section A 4.0 of this appendix are all relevant to Exposure Assessment for ERAs.

4.0 Risk Characterization

The items listed in Section A 5.0 of this appendix are all relevant to Risk Characterization for ERAs. In addition:

- does the assessment clearly identify the potential risk for all relevant VECs?
- are the methods of characterizing the risk appropriate?

5.0 General

- Has the assessment given full justification of all the decisions to not proceed to the next level of ERA for each of the elements of risk assessments (i.e. receptor characterization etc)?
- Has the uncertainty in each element of the ERA been properly assessed, and is the overall uncertainty analysis sufficient for all VECs?
- Are conclusions fully justified in relation to risk characterization and the degree of uncertainty?

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